

Centers for Medicare & Medicaid Services
Special Open Door Forum:
DMEPOS Accreditation

Thursday, January 8, 2009
2:00 pm-3:30 pm Eastern Time
Conference Call Only

The purpose of this Special Open Door Forum (ODF) is to review the accreditation requirements for those DMEPOS suppliers (including pharmacies) that need to meet the September 30th accreditation deadline.

CMS wants to ensure that DMEPOS suppliers have ample time to complete the accreditation process and thus receive an accreditation decision by September 30, 2009. Therefore, CMS is encouraging all enrolled DMEPOS suppliers, except those eligible professionals and other persons exempted by law, to submit a complete accreditation application to an accreditation organization by January 31, 2009.

Background:

Section 302 (b) (1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), required the Secretary of the Department of Health and Human Services (HHS) to establish and implement quality standards for DMEPOS suppliers, except those eligible professionals and other persons exempted by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). All DMEPOS suppliers, except those eligible professionals and other persons exempted by MIPPA wishing to bill Medicare for DMEPOS provided to Medicare beneficiaries, must comply with these standards to receive Medicare Part B Payments.

Pharmacies, pedorthists, mastectomy fitters, orthopedic fitters/technicians, or athletic trainers applying for Medicare enrollment in order to bill for Medicare Part B services are not exempt from meeting the September 30, 2009 deadline for DMEPOS accreditation and are encouraged to participate in this Special Open Door Forum.

We look forward to your participation.

Special Open Door Participation Instructions:

Dial: 1-800-837-1935 & Reference Conference ID: 79431075

Note: TTY Communications Relay Services are available for the Hearing Impaired. For TTY services dial 7-1-1 or 1-800-855-2880 and for Internet Relay services click here <http://www.consumer.att.com/relay/which/index.html>. A Relay Communications Assistant will help.

An audio recording of this Special Forum will be posted to the Special Open Door Forum website at http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp and will be accessible for downloading beginning Friday, January 16, 2009.

For automatic emails of Open Door Forum schedule updates (E-Mailing list subscriptions) and to view Frequently Asked Questions please visit our website at <http://www.cms.hhs.gov/opendoorforums/>

Thank you for your interest in CMS Open Door Forums.

The Audio File of this transcript:

http://media.cms.hhs.gov/audio/SpcODF_DMEPOSPharmFocus.mp3

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Special Open Door Forum: DMEPOS Accreditation

Moderator: Natalie Highsmith
January 8, 2009
2:00 pm ET

Operator: Good afternoon. My name is (Alesia) and will be your conference facilitator today. At this time I would like to welcome everyone to the Centers for Medicare and Medicaid Service DMEPOS Accreditation Special Open Door Forum.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during that time, simply press star then the number 1 on your telephone keypad.

If you would like to withdraw your question, press the pound key. Thank you. Ms. Highsmith, you may begin your conference.

Natalie Highsmith: Thank you (Alesia) and Happy New Year to everyone and thank you for joining us for the Special Open Door Forum on DMEPOS Accreditation. All DMEPOS suppliers except for those eligible professionals and other persons exempted by the Medicare Improvements for Patients and Providers Act of 2008 wishing to bill Medicare for DMEPOS provided to Medicare beneficiaries much comply with quality standards to receive Medicare Part B payment.

Today, CMS staff will review the accreditation requirements for those DMEPOS suppliers including pharmacies that need to meet the September 30th accreditation deadline.

CMS is encouraging all enrolled DMEPOS suppliers except those eligible professions and other persons exempted by law, to submit a complete accreditation application to an accreditation organization by January 31st, 2009.

I would now turn the call over to Sandra Bastinelli who works in our office of Financial Management. Sandra?

Sandra Bastinelli: Thank you Natalie. Good morning and good afternoon. As Natalie said, I'm Sandra Bastinelli and I have oversight over the DMEPOS accreditation program.

And today the purpose is very structured and hopefully very concise. And it is only to review the DMEPOS requirements in light of the statutory deadline for compliance of - and that was the October 1, 2009 deadline that was in statute of July of 2008 as Natalie did say.

Just to give you some background for those of that may - and put this is some context - and before I do that I just wanted to mention that I'm speaking off of a PowerPoint slides that will be of - available to you in the very near future in the next couple days.

So just feel free to - you don't need to take a lot of notes, but just letting you know that these slides will be available to the public once they go through our approval process.

The original statutory (SARI) that implemented actually the accreditation process which actually started with our quality standard and they were implemented on August of 2006. So we just recently this year - fall of 2008 rather, have updated to clarify some of those quality standards. Well, I'll be going over the quality standards in a few moments.

In the statute, we - it does talk about in order to comply with the accreditation requirements that they - CMS would apply these quality standards to certain items for DMEPOS. And they are the DME items, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrition, transfusion, medicine and prosthetic devices, prosthetics and orthotics.

Keeping in mind there is only the covered items. We do have items that are not covered and they are - in particular we get questions on immunosuppressant drugs, anti-viral or cancer drugs, they are - although they are a Part B drug, notice throughout this conference today, I am not

talking about Part B in particular. Although DMEPOS does fall under Part B, this is specific of the DMEPOS benefit under Part B.

So there are certain things that for example, for pharmacy, if you are not going to billing for any of the covered items, you do not need to be accredited. So all of this - if you as a pharmacy do not let's say, offer infusion pumps or enteral/parenteral nutrition or diabetic test strips, they - those things are included in the DME benefit that would require accreditation by October 2009.

However, if you pharmacy that are only billing for your Part B drugs, you will be allowed to continue to bill for those Part B drugs. I will at a later in this conference talk about how for those in particular, pharmacies that may want to not - no longer provide those DME supplies and how to make that change in your enrollment application.

So keep in mind if you are billing for any DME including infusion pumps, then you need to be accredited by the October 1 deadline of 2009. Other - past summer in July, we had a - the Medicare Improvement for Patients and Providers Act - and that's commonly known here as MIPPA.

It did give us statutory (SARI) for the secretary exempt eligible professionals and other persons for meeting this accreditation deadline. The exempted eligible professionals were listed out actually in the regulations by statutes. And they are the physicians, physical and occupational therapist, qualified speech/language pathologist, physicians' assistants, nurse practitioners, clinical nurse specialists, certified registered nurse, anesthetist, certified nurse midwife, clinical social workers, clinical psychologists, and registered dieticians or nutritional professionals.

CMS utilized this discretion to also include other (extensive) (persons). In the MIPPA statute, it did talk about orthotists and prosthetists. In addition, we added opticians and audiologists.

CMS however, does not believe that MIPPA gave the secretary discretion to define persons being exempted as organizational entities. For example, we - it's a - a person is not included for example, pharmacy, which is not a person, it's enrolled as a organizational entity. We did not have the statutory authority under MIPPA at least to exempt the pharmacy as an organizational entity.

Those that were not exempt were those that were not typically licensed or credentialed as those that are exempt persons. And they are the ones that we did give you clarification in December and they are the pedorthists, mastectomy fitters and the athletic trainers. We did not give those other persons exemption at the time.

So if you are billing, if any of those that I just stated, or anyone else that is non exempt, if you are billing or have a billing number which is considered to Part B DME enrollment number or you wish to obtain one between now and October 1 of 2009 or keep it after October 1 of 2009 in order to bill for DMEPOS, you need to be accredited.

Okay, this one goes over the quality standards a little bit and you can find the quality standards on our Web site and I'll give the Web site out at the end as well. And again, I want to repeat the slides will be available on our Open Door Forum Web site in the very near future.

So quality standards are listed under - in two sections and actually three appendices. The two sections are - one are just related to your business standards and a focus on administration, financial management, human resource management, consumer services, performance management, product safety, and information management.

These are standards that are very much your nuts and bolts of every organization of and including performance improvement as what you're looking at to - so far as your customer service base and what supplies you are offering, how to improve your services.

But is also looking at that of which you are supplying is safe by the time it gets to the beneficiary and you know - how can you verify that it is safe. And including - up in to including which is usually very important to some of you in geographic areas backing up your information management in case of disaster.

So it's those kinds of things, (but then most) - but first before you get to any of those standards are administrative, meaning that you have to have someone in charge that is willing - not willing but have the authority to accept all of the responsibility and liability of your organization.

So that's - they are particularly the business standard in addition to, you know, your human resources and that would be all of your credentialing and licensing and certification of your - of the employees and contractors that you have working.

Section two, relates in particular, once you get that physician's order, what you do. So, it's intake and assessment from intake and assessment and education delivery, education and follow-up. So those for you that are clinicians on the call that very much (read) like a patient plan of care and it's supposed to be that way.

So even for those that may not be familiar with, these are medical supplies anyway and we do expect that there is a process that's very smooth and also documented which are policies and procedures here in CMS and regulations do state that physician's orders has to be documented in the medical record.

So these are quality standards that would be looked at on site of your organization to make sure that these things are not just in policy and procedures but you actually have a record of all of your transactions and what has transpired and what you have done to follow up with the beneficiary.

Now the next three appendices may or may not apply to you so you would not have to get accredited. You would only have to get accredited if you're offering respiratory equipment, manual wheelchairs or power mobility including complex rehab or custom fabricated, custom fitted, custom made orthotics and prosthetics, (somatic), ocular and facial prosthetics and therapeutic shoes and inserts.

So just keep that in mind that one of the appendices is all about respiratory, the other is all about wheelchairs and the third is all about orthotics and prosthetics.

So if you're not offering any of those, and they're pretty inclusive in all of those - the appendices, the - only first two sections apply to you.

Now I want to go over the what to expect for those of you that are new on the call. New meaning you've never been through accreditation and I would assume that that's the majority of you, if not all of you. What - where do I even start?

We have this encouraging - encouragement of everyone to get their application by January 30. How do I even get that started? Well, you first have to contact one of the ten approved, which we call deemed - approved accreditation organizations and you obtain information about how to get an application.

How do you do that? Well, we have a list of all ten of them and what they are accredited - or what they are approved to accredit you for on our Web site. Again, I will give - it's the same Web site that I will give at the end of the conference call.

You should - and once you contact the - all of the accrediting organizations have a Web site and once you get on their Web site you will - they also have phone numbers but if you go on the Web site they have applications and you can - and also have frequently asked questions. So you can go through that process.

The accrediting organization is of your choice, not CMS'. So they're all approved and not all of the organizations are approved for all of the product categories that you may be offering, so just pay attention to that, but most of them are. So please, CMS can not opine for you, which accrediting organization would be best to use.

Once you contact the accrediting organization, they will - if you have any questions about what is in the application and what they have to require - what they require in so far as policies and procedures, any kind of timeline and what they're expecting, just - that is specific to the accrediting organization.

We leave that up to them, as long as the accrediting organization has met our requirements which they have for compliance against our quality standards, we leave the actual operational aspects to them.

So please, CMS cannot answer those particular questions about your application, but I would just call the accrediting organization for that.

You as a supplier should apply only for accreditation after you're pretty sure that you're ready, your organization is ready. Meaning if today is the first time you're hearing about accreditation, my guess is going to be a little difficult to get a completed application by January 31.

Just giving the accrediting organization an application that is not complete and just sending in your money will not get you anywhere because it will be held up. It has to be - it does not, you know, there's no clock here other than our statutory deadline of October 1.

So I did that question a lot with, gee I sent in my application six months ago. When I called the accrediting organization, they'll say, yes and we sent them back all kinds of questions and things that - a list of documents that they have yet to send us.

So that burden is on you to make sure that you have all of the documents that the accrediting organization is asking for. A lot of them ask for - many of these things up front. Why? Because first of all behooves you to send that is more streamlined and it focuses the surveyor on your organization prior to the surveyor coming on site.

Now keep in mind also, when you are applying for accreditation, you are required by the enrollment standards and by the enrollment under (855S) to list all of your store locations. And failure to do so, just keep in mind will jeopardize that enrollment if they - if the accrediting organization find more locations than the enrollment contractor, that's an issue because you don't have enrollment numbers for all of your locations.

Also for those of you that may be competitively bidding that will also jeopardize your competitive bid application because all the locations have to be accredited.

Once you submit that completed application, meaning that the accrediting organization has let you know this isn't - has not asked for anything more. By the way, don't expect just adding back and forth all the time, we - if you don't hear anything, unless it's been a long time, I would take that to mean that they have everything they need.

The accrediting organization is not allowed by CMS to give an idea as to when they're coming to do your onsite review; it is unannounced and it is random. So please note that if you're asking for a tentative decision as to when that survey's going to be scheduled, it could be scheduled any time after your application is complete and within, you know, most likely 30 to 60 days before the accreditation deadline.

It does take up to six months, it has been from our experience of 2007 and '08, up to six months to complete the survey process and that is a survey process that everything has gone well and meaning that the application was complete, the organization was responsive, (unintelligible) was responsive and there weren't any major corrective actions that needed to be taken.

So if you are not ready, just keep in mind that's why we're having this call again and that's why we - are encourage you to get - encouraging you to get your application in in January, it's because we're giving you more than ample time to finish this process.

The unannounced onsite survey just going forward in this is once you get accredited, it is an every three year process. There are some accrediting organizations that have some ongoing documentation that is required for process improvement on an annual basis.

However the actual accreditation decision that you'll be receiving is generally unless there are issues and they will tell you that, why they're not giving you a tri-annual accreditation decision. But by and large, most of the accreditation decisions are for three years.

At any time, however, CMS or our designated deemed organizations can and will come on site to make sure that you have complied, you have ongoing compliance with the quality standards.

So just keep in mind that it's not a - we're going to ramp up every three years and we're good to go because you're most likely will not be able to keep your accreditation. And if you can't keep your accreditation you will no longer able to bill Medicare.

Also keep in mind, because of these days being what they are; we probably have more mergers and acquisitions than sales going on in the DME business. Your accreditation decision if your company - you've gotten wind or if you are one of the owners and you're looking to sell your company, I would not get accredited because you can't transfer that accreditation decision.

Once you sell your company, that accreditation decision is null and void. There's no more program, you have to - because the entity will be getting those changes, the sale and you have different ownership and I get that

question a lot. If you have any other questions regarding acquisitions or sales, I would contact the - excuse me, the National Supplier Clearinghouse to Palmetto GBA. And I will give you that Web site in a moment as well.

But just know specifically that there are no - you can't use a bargaining chip in so far as we're accredited, so our company's worth more money. You know, only because the new entity has to get re-accredited.

Okay, the most important thing here and I know I went through the accreditation process quite quickly, but I wanted to make sure they - we have ample time for the hundreds of you that are on the call that may have questions.

Two deadlines, we're recommending at the end of this month, January 31 that you get a completed application in to one of the accreditation organizations to ensure that if you are eligible, you will have an accreditation decision by September 30.

If you need help and where to find those organizations, they are at www.cms.hhs.gov/ - and this is all one word - medicareprovidersup - like supplier - enroll. All one word, no spaces, medicareprovidersupenroll.

On that Web site, you'll not only find the quality standards but you also - there are some fact sheets on there as well. It's also the - all of our DME Web site for enrollment issues that you will also find a link for the Palmetto GBA.

But I'll give you their Web site as well. Palmetto GBA is our contractor where the National Supplier Clearinghouse contracts with this. And that is at www.palmetto.com, P as in Paul, A-L-M-E-T-T-O, G as in good, B as in Barry, A as in association dot com. So it's palmettogba, all one word.

And the next deadline is September 30, but you could say October 1 but by midnight of September 30 you must have accredited - you must be accredited for DME supplies that I talked about or the covered items unless you are currently exempt.

If you choose not to go through accreditation because of - certainly it's your choice, it's a business decision, then please note that you must change your 855S special enrollment agreement application that you have.

And you have - that form can be downloaded with that Web site that I talked about - actually both Web sites you can get an application from them.

But if you're going on the CMS Web site, just look under Tips to Facilitate the Medicare Enrollment Process. And once you go into Tips for Facilitating Medicare Enrollment Process, it'll say forms, 855 forms and then just click on that. Go to the form and you'll actually come up with the application. Okay?

In the near future we will make sure that the National Supplier Clearinghouse also has a Q&A on their Web site describing what you need to, what you need to change, although the application is pretty self explanatory in section one as to what you need to change when you're changing your supplies that you want to offer.

So that is the reason why you have put in your new enrollment application because after October 1 of 2009, if your enrollment application still has any DMEPOS supplies on it and you are not an exempt professional or other person, you will be denied payment through your contractor.

Once you receive the slides we do have an accreditation team and I've - besides myself and I can be reached at Sandra, S-A-N-D-R-A dot B as in boy, A-S-T-I-N-E-L-L-I at cms.hhs.gov. And we have four other staff members and just to save time, I - you will get - you have their names, but it's (Nannette Hardouin), (Alisa Overgaard), (Michelle Arena), and (Daren Djirikian) who does our data analysis.

But the four of us, the first four names that I stated, we are clinicians, so if you have any technical calls, questions, please call us on that.

To - in summary then, I hope that what I've just reviewed in the last half hour, almost half hour were the requirements for how to get started on your application if you have not and what to expect as part of your application process for getting DMEPOS accreditation.

And last but not least, that we have the two deadlines that - and one is statutory and the September 30, 2009 and your application if at all possible, if you could get that in to one of the accrediting organizations that will be helpful.

Last but not least is - in case someone is thinking, what if I get my application in February, will it be - will the accrediting organization still accept it? Yes, they will still accept it, however, just keep in note that it's taken in order of, you know, of how they come in and when they are completed.

So the later you wait, the more cost there is - more of a greater possibility that the accrediting organizations will not be able to process your application. And the accrediting organization would let me know that at the time.

Natalie, I'll open it up to questions at this time.

Natalie Highsmith: (Alesia), if you could just remind everyone on how to get in to the queue to ask their question and everyone please remember when it is your turn to restate your name, what state you are calling from, and what provider or organization you are representing today.

And please be mindful that we do have several hundred people on the phone lines. So if you have multiple questions, if you could limit it to two questions and if you have further questions, get back in to the queue to ask your other remaining questions. (Alesia)?

Operator: Yes ma'am. At this time I would like remind everyone if you would like to ask a question, please press star then the number 1 on your telephone keypad.

We'll pause for just a moment to compile the Q&A roster.

Our first questions comes (Brian Apple). Your line is open.

(Brian Apple): Hi, this is (Brian Apple) from Dean Pharmacy in Wisconsin. You stated that all locations must be accredited. So if I have a chain of pharmacies and one of them does not process any DME or any diabetic supplies, I still have to get that one accredited? Or did I misunderstand?

Sandra Bastinelli: That's a good question. Thank you. The survey - or excuse me, the accreditation decision is for your entire chain. So to the extent that you don't have - you would note that in your application that that location doesn't process any supplies that are DME supplies, they only do drugs - you know, they only furnish biological drugs.

(Brian Apple): Okay, thank you.

Operator: And the next question comes from (Shelly Farlow). Your line is open.

(Shelly Farlow): Hi, my name is (Shelly Farlow). I am from Maryland in (unintelligible) Management Services. I actually just missed the first part of your email address and I needed to get that.

Sandra Bastinelli: Sure. My name is Sandra Bastinelli and that's spelled in my email is Sandra, S-A-N-D-R-A s- a- n- d-r-a dot B as in boy, A-S as in Sam, T as in Tony, I-N as in Nancy, E-L-L-I- l and it's at cms.hhs.gov.

(Shelly Farlow): Okay. And then all the links that you - you know, when you have this come down as a PowerPoint, it'll be on that CMS Web site that you gave...

Sandra Bastinelli: Yes.

(Shelly Farlow): ...the Medicare provider, that's the Web site that we can go to?

Sandra Bastinelli: Yes, you can.

(Shelly Farlow): Okay, thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Gayle Dunbar). Your line is open.

(Gayle Dunbar): Yes, this is (Gayle Dunbar) calling from Yakima Washington Home Infusion. And we are already accredited for the hospital side and the home health side. And when I contacted Palmetto, they stated that we just didn't have the DME portion on our accreditation. So they instructed me just to send a letter to them to ask them to add that.

Now, once they add that, does that automatically cross over to the information to you guys? Or do we need to then do a new enrollment?

Sandra Bastinelli: That's a great question. Thank you so very much. What I would do now, certainly comply with whatever the NSC has asked you to. However, what's most important is to make certain that you are accredited under the DME quality standards which I'm sure you are.

But please contact your accreditation organization because of their statistics or their data that they give us on who was accredited and we actually have product categories that link with your enrollment application.

If - you could give anything to the NSC, but if we do not have the information from the accreditation organization that they actually accredited you for any DME supplies, you will not be considered accredited. So please contact your accrediting organization to make sure of that.

(Gayle Dunbar): Okay, so once they - if they go ahead and add it because they did review us at the same time, they just - it was not part of the - I guess, the application when we sent it in. So once they add that, does that - crosses over automatically? Or do we have to do a new enrollment?

Sandra Bastinelli: No, no. Whatever the NSC needs, your - whatever they said they needed is fine.

(Gayle Dunbar): Okay.

Sandra Bastinelli: Don't do anything more than what they - you know, don't submit anything different. Whatever they ask for, whatever documentation they ask for, just go ahead.

(Gayle Dunbar): Okay. Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Andrea Logan). Your line is open.

(Andrea Logan): Hi, yes we have already been accredited and - I'm in Michigan, I'm sorry. (All Care Billing). And I'm wondering if we have to notify NSC or anybody else that we've been accredited, will the accrediting agency - and I think you referred to it a little bit on the last call - follow through on that?

Sandra Bastinelli: Okay, if you've been accredited by - and just keep in mind that when you say you're accredited, if you've been accredited before 2007, you are not accredited for DME, that I can assure you because we did not have - there were no accrediting organizations that started before January of 2007.

So if you were accredited before then, it was not for CMS DME quality standards. So having - assuming you were after that date, and if that is the case, then we do keep data, our accrediting organizations give data to us that is shared with the NSC as to who was accredited for what.

(Andrea Logan): Okay. Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Lisa Odum). Your line is open.

(Lisa Odum): Hi, (Lisa Odum) in Missouri with The Sisters of Mercy Health System. Can you just clarify if an optical group office that would be doing DME for post cataract glasses and lenses, are they required to be accredited?

Sandra Bastinelli: Most likely you have opticians and ophthalmologists supplying those products and they are exempt.

(Lisa Odum): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Elizabeth Jayer). Your line is open.

(Elizabeth Jayer): Yes, you had mentioned earlier that you would give us some information about if we decide not to be accredited and certain categories, how to handle those beneficiaries. Like say for instance, a bed rental or something that we're doing currently but we're - we've decided maybe not to do that in the future and not be accredited to do any type of rentals. How do we handle our current rentals?

Sandra Bastinelli: Well, that's out of the scope of this call because I don't have the subject matter expertise to - however, there are - CMS does have extensive policies and procedures in their manuals as to the transferring of beneficiaries to another DME supplier if you choose not to - you can't just drop the supplier.

And as it relates to beds, I, you know, I know there's been a lot of new information on oxygen but I'm sorry we don't have the folks in the room that can answer that question.

But maybe if you could give us your name and phone number, I can - or your email address, I can - we can make sure we - or you can just email me, I'll make sure the correct area states that. I did give information as to what you would need to do for enrollment purposes. Was that clear enough?

(Elizabeth Mayer): Yes. I did understand that part and I will email you and give you my information because we called CMS and - our CMS that we deal with and they were not any help at all. So, anybody that you can send me to would be great. So I'll email you and give you my information.

Sandra Bastinelli: Okay, and let me know who was it if you can remember who you spoke with so we get you to the right person.

(Elizabeth Mayer): Great, thank you.

Operator: The next question comes from (Billy Cooper). Your line is open.

(Billy Cooper): Yes, I'm (Billy Cooper) from (West Lake), Michigan. In the beginning my actual firm name was (Old World DME) but because I'm a sole proprietor of Medicare - or CMS had recommended that I change to my actual name.

However, I've been considering and in the process of incorporating and - does it (deem) that it would cause a problem right before the deadline in January or in between of the deadline?

Sandra Bastinelli: Yes, good question. I would - since you have a change in your ownership from - it's not really an ownership but it is a change, somewhat from sole proprietor to - I would go back on the Web site that I spoke of and get a revised form, your 855S.

(Billy Cooper): Okay.

Sandra Bastinelli: And follow that. Are you accredited now, sir?

(Billy Cooper): No, I'm not. I've been approved only of the course of a year.

Sandra Bastinelli: Okay, so you've been a Medicare provider for a year?

(Billy Cooper): Since November of the previous year.

Sandra Bastinelli: Okay. What I would do is do that very quickly. However, I have to say that most the - your application, I wouldn't send that in before you get accredited. But you can ask.

You can simply - in this case, you are not accredited. So you need to be accredited if you want to bill. It's not going to make it more difficult for you; it's just that you have to do one extra step. You have to make sure you change your NSC application and you still have to get accredited by October 1 of 2009.

But that would not certainly hold up your accreditation. Just let the (accreditors) know you're a new, you know, Limited Liability Company or whatever. They'll ask for those corporation forms.

(Billy Cooper): Okay, very good. Thank you.

(Sandra Bastinelli): You're welcome.

Operator: The next question comes from (Jackie Cheevers). Your line is open.

Sandra Bastinelli: Hi, (Jackie)?

(Jackie Cheevers): Some durable medical equipment like catheters and vacuum erection devices and so that's about it. Would we be exempt or do I need to be accredited?

Sandra Bastinelli: Those items are considered durable medical equipment by Medicare and under the statute, so you would need to be accredited.

(Jackie Cheevers): We would be?

Sandra Bastinelli: Yes.

(Jackie Cheevers): Okay. Even though we're a physician office? I'm not a pharmacy; I'm not a home health or anything like that. We mostly see patients for urology problems, but there are a few DME supplies that we do sell.

Sandra Bastinelli: Yes, that - the latter of what you just said puts you in to that category, the latter.

(Jackie Cheevers): The vacuum erection device?

Sandra Bastinelli: Well no, not just the vacuum erection devices but the fact that you sell products outside of the physician's, you know, confines. We could do talk - since your situation may or not be exempt - since I don't feel comfortable that I have enough information, why don't you give me an email?

(Jackie Cheevers): Okay.

Sandra Bastinelli: Okay?

(Jackie Cheevers): All right.

Sandra Bastinelli: Because I don't want to give you the wrong information.

(Jackie Cheevers): Or the accreditation can tell me if I'm exempt or not, correct?

Sandra Bastinelli: Yes, that would be me, yes.

(Jackie Cheevers): Okay, all right. Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (David), I'm sorry, (Dave Verhealth). Your line is open.

(David Verhealth): Hi, (David Verhealth) calling from Iowa. We're a very rural location. We have a county of about 9000 people. There are no DME suppliers in the county, within 20 miles any direction; there are no other pharmacies within 20 miles every other direction.

Right now, we're stressed just spending the hundreds of hours and thousands of dollars complying with our pharmacy requirements, meeting HIPAA privacy, HIPAA security, policies and procedures, Medicare fraud training, and we have been providing DME products more as a service to our patients than anything else.

We do about \$20,000 a year. It's going to cost me over \$4000, to say nothing of the time, just to apply for this accreditation with the organization that is the least expensive for us. Obviously for \$20,000 a year, we were barely breaking even to begin with. There is no way we're going to spend \$4000 to do this accreditation.

My question is, has CMS considered what they're going to do for my patients in my county that have no other options?

Sandra Bastinelli: Thank you, yes. Those questions actually - those issues were addressed quite extensively with the competitive bid process in so far as access to delivery of most likely the supplies that you offer in pharmacies. And that is by way of national chains or mail order supplies, which I have to tell you sir, my parents are - live in actually - probably a little over 500 folks in a village.

And they do not have - (unintelligible) is a problem but the availability to get out by car and they do have mail order that has been very convenient for them for diabetic supplies and other such supplies.

So other than saying that - we do hear you. We thought that we have answered the access question and the other certainly is a business decision but I do understand as a clinician; trust me I do, for the rural pharmacies in particular, it is a cost issue considering how little of the volume that you do, that you do provide. And the only thing I can say is that we did not find anywhere in the United States that it was an access issue.

It certainly would be an access issue if they - the beneficiaries only choice to drive, but considering that the average age of our beneficiary is quite elderly, I'm not certain that that probably would be as much of an issue as if we did not have mail order companies.

(David Verheath): Okay. Then what do I tell my patient that's 80 years old that has acute bronchospasm that the doctor sends down to the pharmacy for a nebulizer?

Sandra Bastinelli: The nebulizer is a drug and you do not - you can still offer that as a Part B drug. So that's not under DMEPOS.

(David Verheath): That's fine. This patient comes to me and I say, gee I can give you the solution but you're going to have to drive 20 or more miles somewhere to get the compressor and mask or mouthpiece to be able to administer this device.

And it's the same thing for diabetics. That's not as acute a situation but you are leaving an entire county without acute service. And by the way, mail order service of these supplies does not eliminate the need to talk with these patients and fix their glucose monitors when they go bad or change the

battery when they go bad or any number of things that can't be done on a timely basis by mail order.

Sandra Bastinelli: I agree with you whole heartedly sir, and anyone that we do accredit, they do need to have follow up, including mail order if it's a matter of having a subcontractor.

If they provide services, they have to provide respiratory services 24 hours a day, seven days a week. And that is a requirement. So if they are not doing that, we cannot accredit them. So absolutely, your point is well taken and we do expect that of any of our suppliers.

(David Verheath): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Beverly Rugol). Your line is open.

(Beverly Rugol): Hi, I was just wondering if we can remain as a non assigned participating provider should we choose not to become accredited. Do we have to fill out a new 855S?

Sandra Bastinelli: I'm sorry, I heard part of that, but you're changing your supplies?

(Beverly Rugol): I'm sorry. Should we choose not to - we're in - sorry, (Drug World Pharmacies) in New York.

Sandra Bastinelli: Okay.

(Beverly Rugol): And should we choose not to become accredited and we have to fill out a new 855S application, can we remain as a non assigned participating provider?

Sandra Bastinelli: Yes, sure. Absolutely. You just need to change, you know, when you go into the application as you know, it sounds like you're quite familiar with it, it tells you - yes, what you're taking off, yes.

(Beverly Rugol): Okay.

Operator: The next question comes from (Dennis Jenning). Your line is open.

(Dennis Jennings): Yes, I'm in Kentucky and I work for (Coram Home Care) and I think my question's just now answered. Part of - we have a drug store that's just a walk in and it's listed on our form as a provider but my supervisors wanted to know how to revise the application if we're not going to participate. So that was 830, now it the 855S?

Sandra Bastinelli: Yes.

(Dennis Jennings): Okay. Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Robert Scherbier). Your line is open.

(Robert Scherbier): Hi, my name is (Robert Scherbier) from Morrisville, Pennsylvania outside of Philadelphia. My question is an individual pharmacist, is that individual pharmacies and their staff must go through this process, spending hundreds of hours, thousands of dollars, yet, we're told the chain has got a blanket certification at the corporate level and none of their staff has to go through the same training. Why is that and how do you justify it?

Sandra Bastinelli: Great. That's an easy question. I can't justify it because it did not happen. So the fact you have been told it was - is a rumor and it's not true. I've been to the - on site with the accrediting organizations during most of those national pharmacy chains and they were in fact on site visited. As well as interviewing other staff and I was one of them who did interview them.

So I cannot verify that's what you are saying is true. So to answer your question...

(Robert Scherbier): So you are saying that each individual outlet of a national chain, their personnel is trained and certified - or accredited?

Sandra Bastinelli: Yes they are. And how they do that are two different ways. One is on site surveys. The other's a review of documentation from the other - from all of the locations, including checking licenses and/or certificate appropriate.

(Robert Scherbier): Okay and my second question, why weren't community pharmacies doing a low volume of DME, (but) some diabetic supplies not exempt from this overwhelming program?

Sandra Bastinelli: Well, as I stated and under the Medicare Improvements for Patients and Providers Act of July of 2008, we did not believe that the secretary had discretion to exempt organizations. And the statute was very clear that it said professionals and other persons. And pharmacies are considered organizational entities.

So we have been in contact actually with the National Community Pharmacy Association and dipped into many - three other national associations quite a bit along with the Congressional staff that are interested in the same topic you are. And we have explained that and basically we believe that your organizations were looking for a statutory change in that language.

(Robert Scherbier): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Mariah Goody). Your line is open.

(Mariah Goody): Hi, this is (Mariah) for a (Hoyt Eye Care Center LLC) located in Maine. You had mentioned something about opticians and ophthalmologists as being exempt. However the practice that we bill for is the center - the practice itself. And they do have a DME that was approved on 11-1-2007. Do I need to go ahead and reapply now for this?

Sandra Bastinelli: I'm not sure what reapply for what? Are you - if you're a DME supplier, the fact that - if your application stated opticians, you know, the supplies that you're - as ophthalmologists and opticians, the NSC would automatically know that that's all you were doing and you would be exempt. So, I'm not sure what the question is, reapplying - meaning changing your enrollment application?

(Mariah Goody): Well you were saying about having - most of these places need to be accredited. But if we just got approved through the DME and NSC back on November 1st, do I need to do any re-accreditation or anything like that...

Sandra Bastinelli: Well just so you know, what you have is not an accreditation. What you have is a Part B number to bill Medicare. NSC does not give out accreditation. That's - what we're talking about today has nothing to do with the NSC. It has

to do with something about the enrollment application. It is getting accredited.

But send me an email, so I know what it is that is that you are billing for to make sure that you are exempt from accreditation. I can't tell from what you're asking me - if you are the company that you are billing for is actually exempt from accreditation yet. But if you don't mind sending me an email, that would be great.

(Mariah Goody): I can do that. Any requirements that you want on that email?

Sandra Bastinelli: No, just what you just said.

(Mariah Goody): Okay.

Sandra Bastinelli: And what - who - what actually are - you know, who's in the organization and what the supplies are.

(Mariah Goody): Okay.

Sandra Bastinelli: I don't have access to your enrollment application so I would have no way of knowing.

(Mariah Goody): All right. Thank you.

Sandra Bastinelli: Yes.

Operator: The next question comes from (Mitchell Miller). Your line is open.

(Mitchell Miller): Thank you. My name is (Mitchell Miller) from West Babylon, New York. I have question about the surety bonds - surety bond that's been posted. I read this on the Web site. I wanted to know if that's going to (come through), we have to post a bond, a \$50,000 bond even if you're accredited?

Sandra Bastinelli: Yes, I believe that's true although I'm not the expert on surety bonds. If you'd like more information and have other questions, however, on the Next Open Door Forum for DME, its home health and hospice which is Thursday the 22nd. I believe that's a Thursday, it could be Wednesday, but January 22 that I do know, at two o'clock there will be someone, a representative that wrote the surety bonds regulation will be talking about that regulation in particular.

(Mitchell Miller): Thank you.

Operator: The next question comes from (Norman Levin). Your line is open.

(Norman Levin): Good afternoon. (Norman Levin), pharmacist, Baltimore, Maryland. Is the -
if my business is all in store for diabetic supplies, do I need accreditation?

Sandra Bastinelli: Yes sir, you do.

(Norman Levin): If I would change to mail order, would that change my status?

Sandra Bastinelli: No, it would not. They're considered DME supplies.

(Norman Levin): You saying no it would not?

Sandra Bastinelli: No, you would not be exempt.

(Norman Levin): Accreditation then?

Sandra Bastinelli: That's right.

(Norman Levin): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Karen Christian). Your line is open.

(Karen Christian): Yes, I have two questions. One is if a new pharmacy is opening within the
next few days or weeks, they work to be a Part B provider for the drugs only
but down the road they wanted to do accreditation, how do they go about -
provide that form to change their provider number after they get accredited?

Sandra Bastinelli: Okay, good question. First if you're starting off just with a Part B provider,
you know, you're going to list everything that you hope to provide. And if
none of it is DME, it's just biological, then that application will go right
through for processing.

If however, you want to add DME supplies, I would suggest that you hold off
on your application and contact one of the accrediting organizations and get
accredited first.

Okay, so you said down the road you want to add it, all you do is the same thing of (unintelligible). But before you even change your application, get accredited because your change in application will be revoked, will actually be - not revoked, it will be returned to you. Because you weren't accredited for those DME supplies, you cannot bill for those DME supplies after October 1, 2009 until you get accredited for those.

(Karen Christian): Okay. If you want to be accredited after '09 you decide, wait a minute, I need to be able to serve my customers, you can go back after '09 and get accredited?

Sandra Bastinelli: Oh, absolutely.

(Karen Christian): Okay.

Sandra Bastinelli: You can't after '09's bill, that's the issue.

Karen Christian: Right.

Sandra Bastinelli: You can't bill Medicare, but absolutely, you can get accredited any time you choose. We're just warning - I should say - (warning) probably is a strong word, but that is true that we want to make sure that there is no business disruption for those of you that are counting on billing Medicare for those DME supplies after October 1, 2009.

But certainly if you're not billing and you don't choose to then that's a business decision of yours.

(Karen Christian): Okay, thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Lori Wolfe). Your line is open.

(Lori Wolfe): Hi Sandra. This is (Lori Wolfe) from Cardinal Health in Dublin, Ohio. I just want to confirm a statement that was made a couple calls back regarding participating versus non participating suppliers. And that under both circumstances you need to become accredited.

And I believe one of the questions that somebody was asking was can I just change my status to non participating and not become accredited?

Sandra Bastinelli: Yes, hi (Lori), it's Sandra. Yes, I, you know, certainly if they're not accepting assignments, you're not accepting assignments, I don't, you know, know what the - I have to assume that if you're not, you're not billing. If you could choose to bill Medicare, then you have to be accredited. So it just relates to the billing either - but if you want to change your status, certainly that's a business decision.

(Lori Wolfe): Right.

Sandra Bastinelli: For billing.

(Lori Wolfe): If you change your status to non participating though, you're still required to file a claim for every Medicare beneficiary for every covered item or you turn the customer away just - difference between participating versus non participating is who gets the check.

Sandra Bastinelli: Understood.

(Lori Wolfe): Okay.

Sandra Bastinelli: I'm not the expert in non participating and participating however. Just keeping in mind the advanced beneficiary notice if you are not - if the beneficiary - so the beneficiary knows that this is a covered item and then Medicare would pay for that covered item but because you're not accredited, you can't bill for that item. But yes, - so yes, if you are billing - continuing to bill Medicare, thanks for that clarification, absolutely, you'd have to get accredited.

(Lori Wolfe): Okay, whether it's participating or non?

Sandra Bastinelli: Right.

(Lori Wolfe): Okay. Thank you.

Operator: The next question comes from (Albert Hesse). Your line is open.

(Albert Hesse): Yes, (Albert Hesse) from (King Cohen Pharmacy). Actually I was asking a question about the surety bond and you answered that. You have to talk to another person about that, so. Thank you.

Operator: The next question comes from (Shelly Farlow). Your line is open.

(Shelly Farlow): Hello, this is (Shelly Farlow) from Maryland. My question is if we're a skilled nursing facility providing PT/OT and Speech but we also have outpatient services as well and all of these disciplines and we have nurse practitioners in our building, do we have to get accredited?

And if we do, do we also have to do this with our two additional nursing facilities that do not provide this service?

Sandra Bastinelli: Okay, hi. Well, to try to keep it simple because there's so many different styles out there, it really if you break it down to what it is you're billing for. DME, the fact that you're offering the outpatient services may be under - well, I'm not going to make any conjectures as to how you're billing for that. But the supplies that you are giving out to those patients under those occupational therapy, physical therapy visits, I'm assuming fall under DME.

And then I'm assuming that you have an enrollment number for those supplies. If all those things are true, then this entire conversation about the accreditation deadline applies to all of your skilled nursing facilities, yes, to retain that Part B DME portion of your billing number.

But if what I said was not true, again, give me an email and I'll be happy to get that throughout the - our other policy experts.

(Shelly Farlow): Okay, because we have actually applied probably a good six months ago and we haven't heard anything. So I'm wondering since you said there could be a hold up if that's maybe the hold up.

Sandra Bastinelli: What did apply for? I'm sorry.

(Shelly Farlow): The accreditation for the DMEPOS accreditation.

Sandra Bastinelli: Yes, let me - please, send me an email. I need to know that.

(Shelly Farlow): Okay.

Sandra Bastinelli: Six months is a long time, so.

(Shelly Farlow): Okay, thank you.

Operator: The next question comes from (Paulette Savvant). Your line is open.

(Paulette Sauvart) Yes, I'm calling from (Kohler Home Care Pharmacy) in Arlington, Texas. And I wanted to go back to the issue about the pharmacy and pharmacists being accredited. The statement I believe I heard Sandra make was that - considering whether or not pharmacists - pharmacies should be accredited was based on it being an organization. But the pharmacist that is running the pharmacy is a professional. And so why wouldn't the consideration be as a professional rather than an organization?

Sandra Bastinelli: That's a wonderful question. And I have to tell you, we - this is not an aside or a personal front to the pharmacists, that CMS does not believe that they're professionals, not at all. First of all by statute, CMS did not define, Congress defined who was considered a professional, that's number one.

And number two, the other professionals were considered, those that were persons that were enrolled as persons. The pharmacist that being the person is not enrolled to bill Medicare under Part B DME as a pharmacist.

They enrolled because, from what I understand, from your organization, that a state licensure requires you to be enrolled as organizational entities. So that fortunately falls under your state licensing. And because of state licensing, you have to comply and have to actively come in as a Medicare provider as an organizational entity.

I also would like to - for you to note that - however, not a consideration, please note that although under an organization that just has one pharmacist a year, she does all of the billing and actually is pretty tightly controlled. That is not the concern of CMS. We wish that was the case throughout the country. However, that is not the case and we do have instances of fraud and abuse throughout.

And they're not with the national chains either. We have instances that we have found fraudulent professionals using. And I know the argument can be made, well, they'll - they are licensed by the state and the state will take care of that. Well, it still occurs.

So we just - it's just one more reason that we really did not have any wiggle room in the statutory - the statute that was written in July of 2008 nor did we believe that it was Congress' intent to do that.

So as I said, is your organizations are looking at other areas but I don't know what else I could tell you on that.

Natalie Highsmith: Okay. Next question please.

Operator: Your next question comes from (Robert Shriver). Your line is open.

(Robert Scherbier): Hi, (Robert Scherbier), Pennsylvania. Was CMS's intent with the accreditation policy to lessen competition by forcing smaller suppliers to drop out of the network?

Sandra Bastinelli: No, it never is our intent to - certainly we understand that some things do drive economy or business decisions and it looks as such. The Congress' intent for quality standards were just that, quality standards. And the accreditation process is the compliance with those quality standards.

And reading those quality standards it is about the safety of - and the quality of services that beneficiaries receive. And it has been throughout historical backgrounds that accreditation services do - or accreditation standards do increase that quality. So, no, the rest certainly was not a consideration at all.

(Robert Scherbier): Could I ask you honest opinion of what you think this is going to do to the marketplace?

Sandra Bastinelli: If I could answer that I probably wouldn't be at CMS. I have no idea. Gosh, I'm sorry, I'm not certain if I understand the question even, but I...

(Robert Scherbier): The question is, because of the burden of this on a small individual operation most of them or many of them are just going to throw the towel in because it's too expensive to comply with what CMS is asking us to do.

Because of that, you're going to be left with all the major corporations as being the only suppliers of products. And to me it looks like that was their intent to lessen the number of billers and not have to work with as many providers.

Sandra Bastinelli: No, I mean that's certainly never a consideration and I just need everyone to know on the phone that we have almost 25,000 pharmacy locations already accredited and that includes small owners that have already become accredited as pharmacies.

So I - we don't see any trends of that occurring to date.

Natalie Highsmith: Okay. Next question, please.

Operator: The next question comes from (Linda Corbell). Your line is open.

(Linda Corbell): (Linda) from Seattle, Washington, Northwest (P&O) Clinic. We do prosthetics and orthotics. As a question, we are accredited with ABC, already have been for a number of years, do we still need to do a new accreditation?

Sandra Bastinelli: No, you're good to go. Congratulations. Good luck.

(Linda Corbell): And also we have a mastectomy fitter here. Now, does she have to do a separate accreditation?

Sandra Bastinelli: (Will - is your) mastectomy fitter billing?

(Linda Corbell): We bill under - not under her own individual number, no. We bill under the company's number.

Sandra Bastinelli: Yes. You can give me an email but I just - I did talk about that. If you continue to bill, a mastectomy fitter is not exempt. The mastectomy fitter is not billing. So...

(Linda Corbell): Okay. But our orthotists and prosthetists are okay?

Sandra Bastinelli: Your - the services that you're providing are exempt.

((Crosstalk))

(Linda Corbell): They don't individually have to be separately accredited?

Sandra Bastinelli: No, no. And you're already accredited anyway. So you're just doing so well.

(Linda Corbell): Okay. And then I just want to double check on this because there's one thing, we had said if we enrolled with the NSC clearinghouse prior to March 2008, we must submit accreditation documentation.

Sandra Bastinelli: Yes.

(Linda Corbell): But we were accredited with ABC like three years ago and it's up later this year, so we'll obviously will be visited again.

Sandra Bastinelli: Sure. They have your accreditation on file because we have it on file.

(Linda Corbell): Okay.

Sandra Bastinelli: So, not unless, you know, your - there's a separate billing number for that mastectomy fitter, then that person would have to get accredited, yes.

(Linda Corbell): Okay. Thank you.

Sandra Bastinelli: Yes.

Operator: The next question comes from (Kim Gracie). Your line is open.

(Kim Gracie): Hi, this is (Kim Gracie). I'm calling from (Penn Tech) in Pennsylvania. When - the accreditation, is that only for like Medicare patients? Because when they're coming in are they just looking at the Medicare patients or are they looking at the whole population of our patients, rather their commercial patients with no Medicare?

Sandra Bastinelli: Thank you for that question. CMS only has, for this statutory provision only has the authority to look at the Medicare population. The surveyor has no authority to look at any of your private insurers or Medicaid records, actually under this accreditation process. It could under another but as it relates to DME, no. Only Medicare records are what they - only Medicare processes as they relate to these (quality) standards are they allowed to look at.

(Kim Gracie): So that's generally like the active patients that are on then, the Medicare active?

Sandra Bastinelli: They make look for discharged patients. I - you know, they may look at discharge records as well. Now keep in mind, some of your accrediting

organizations may ask - they don't just accredit for Medicare. Obviously, no one does. So they may - they do have to tell you however if they are accrediting you for, you know, outside, meaning they have standards outside CMS's standards and they would ask for other records.

But not for your Medicare accreditation status would they be looking at those records. We understand from many of you that you need to be accredited for private contracts, private insurer contracts. So if you're getting accredited, you know, if you're asking for accreditation for those purposes then they would be looking at everything. But in this case, this would only apply for Medicare.

(Kim Gracie): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Becky Straley). Your line is open.

Sandra Bastinelli: Hi, (Becky)?

(Mike Patton): Hi, this is (Mike Patton). I work with (Becky) at the (Elmaway) Pharmacists. One simple question, does this apply to billing for Medicare Part D as in dog or just B as in boy?

Sandra Bastinelli: Yes, just B as in boy.

(Mike Patton): Okay. Thank you very much.

Sandra Bastinelli: Oh, you're welcome.

Operator: The next question comes from (Tracy Rivers). Your line is open.

(Tracy Rivers): Hello. My name is (Tracy Rivers) and I'm calling from Memphis, Tennessee. I work for (Fred's) Incorporated. And we have franchise pharmacies, about four or five of them and I wanted to know if there's any difference ~~in~~ between the accreditation for them and for our regular chain pharmacies.

Sandra Bastinelli: Franchisees are not considered chains. First of all you have to have 25 or more locations then we could talk offline about a franchisee as opposed to what we consider is a chain with a like parent and a governing body.

But we would most likely just from the information that you gave me, each of your franchise would have to go to separate accreditation (decision) - you can certainly choose to use the same accrediting organization. In fact I would encourage that. But they would all get separate accreditation (decisions).

(Tracy Rivers): All right. Just a follow up question. So when I talk to accrediting agency, they would already know that information and help me work through that?

Sandra Bastinelli: No, they'll know the information that you tell them.

(Tracy Rivers): Yes, that's what I mean, if I tell them that we have...

Sandra Bastinelli: Yes.

(Tracy Rivers): ...(unintelligible) they'll know how to help me work through that.

Sandra Bastinelli: Yes, absolutely, absolutely.

(Tracy Rivers): Okay.

Sandra Bastinelli: Thank you.

(Tracy Rivers): Thank you.

Operator: The next question comes from (Elizabeth Sayer). Your line is open.

(Elizabeth Sayer): This is my question. About 50% of our Medicare business is post mastectomy, which is our primary focus. And we do some (neurologicals), (ostomies), (unintelligible) as well. The post mastectomy business is really the only business that we're doing any assignment in. All the other claims we do unassigned.

I just want to clarify this to be on the safe side. If we get accredited in our post mastectomy business, we cannot bill the (list payers) as an unassigned claim, can we, if we remove that from our CMS 855 application?

Sandra Bastinelli: That is correct. I would suggest that you get everything accredited. There would be no reason for you to remove it, but, you know, that's certainly a business decision.

(Elizabeth Sayer): Right. So if that box is not checked then there is no billing for it either way no matter what, unassigned or assigned.

Sandra Bastinelli: Yes, I don't know how there would be under their enrollment application.

(Elizabeth Sayer): Okay. All right. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Amma Amilia). Your line is open.

(Charles): Okay. This is (Charles), I'm calling from California (unintelligible) Pharmacy. And I'd like to know how much is the fee, the enrollment fee for the accreditation?

Sandra Bastinelli: Okay. There is no fee for the National Supplier Clearinghouse to receive a number to bill Medicare. That's - I don't believe there is any application fee for that. For the accrediting organization, it depends. It can start - and keep in mind these are three year costs, not annual costs.

(Charles): Yes.

Sandra Bastinelli: So when people are talking about \$4000, that's not - that's over a three year period. So on an average, and I just received their cost for 2009, on an average for someone that has one location, on average it would be about a little over \$1000, \$1500 a year.

(Charles): Okay. So it's - and the year starts from January 31?

Sandra Bastinelli: The year starts from whenever you get accredited. But the actual application fees could be - is always included in that price. So it could be a couple of hundred dollars and, you know, I don't, you know, most - a lot of them don't have actually application fees, they just include it in with their prices.

But for those that do, just to submit an application doesn't cost you \$1500, no.

(Charles): Okay. Okay. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Billy Cooper). Your line is open.

(Billy Cooper): Yes. I came basically from the automotive industry and as - actually, I was (unintelligible) (ISOP 16 9 49 2002). So a lot of the requirements for the accreditation is in many ways is very similar because of the (prices) approach.

But because - and my question is - I'm not familiar with the registrars of the medical - for this particular audit. And I was wondering are they staffed enough to handle the volume? And based on what I've heard today, the fact that there's only 25,000 pharmacies, so that means there's a lot more pharmacies that would have to go through the process.

And should a pharmacy or any DME, which would not be my firm, but should any of those firms falter and not be able to meet that deadline even if they've been given time to - I assume there's an opportunity to (provide corrective actions).

(And is it kind of) hidden question involved. But what would happen if a DME because of such, decided to pull out completely, what would happen, how would - would those patients be transferred to other DMEs? How would it be handled because obviously they could no longer afford in many ways to provide services?

Sandra Bastinelli: Yes. Well, there would have to be a transition period for that - for that supplier to transition to another but, you know, to another supplier that can bill Medicare.

However, they can - the supplier can continue, which some suppliers, can continue to supply the whatever they are doing. Since they already received billing (rental) for example on a supply (unintelligible) that that beneficiary gets transferred.

Transfers happen all the time in Medicare for DME services. So this would be not unlike any other and we don't anticipate in a large amount of transfer of beneficiaries.

The first question was is there enough of a - enough surveyors to deal with the volume? Yes, there are. All of the organizations have ramped up, actually over a year because of the competitive bidding program and have been

continuing to add new staff and training them. Even though they are all professional staff, they have to be trained in (the quality) standard.

(Billy Cooper): Yes.

Sandra Bastinelli: So, they are ready to go and have been even after the deadline was announced and they are not overworked right now.

(Billy Cooper): I hate to add another question, but I think it's key. Does the - I think it's important for everyone - and I apologize for my hoarseness - but does the - is there like a training or certification for the registrars - I'm just trying to get a feel for it - to where the auditing process that each of the ten (perform) or are they going to quite similar or are they going to - is it a possibility it will be significantly different?

Sandra Bastinelli: Well, I hope there's not a possibility that they're significantly different because I have done the training myself for all of them and of course when they train their surveyors.

As it relates to any guidance that has been given to the public, yes I actually did do a training for an entire afternoon on the quality standards and how you could comply with those standards. And certainly we can continue to do so in this coming year in the beginning of 2009 if we find that that is still a problem.

But we - all of the (accreditors), all of their policies and procedures in addition to their quality standards, interpretation of those quality standards is not secret. They are all in their manuals that you purchase for accreditation. And there should be no reason to be surprised when they come on site to what they are looking for.

(Billy Cooper): Okay. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Debbie Berringer). Your line is open.

(Debbie Berringer): Hi. This is (Debbie Berringer) and I'm from Boise, Idaho and I'm with (Abbott Steins LLC). We have about 250 pharmacies and first off I can tell

you that the auditors will come and we have had probably about 50% of our pharmacies were audited for that unannounced survey.

My question is though, with new or acquired pharmacies, on a go forward after your accreditation are they grandfathered in or is there another process that you have to do once you have - either build a new pharmacy or you acquire one from a different company?

Sandra Bastinelli: Right. The first thing you do is - well there's two things to do. You let your accrediting organization know, especially if it's after October - oh, anytime but after October 1 you - and anytime you need to update your 855S as well. So you have to add that location and then you have to call the accrediting organization.

They will generally - it's not a grandfathering but depending on when your next accreditation decision is up you may be up for a re-accreditation in the next couple of months. They'll just let you know that, you know, thank you very much for the information, we'll include that in our next training- our next survey.

Or they may decide to come out because of the high volume or where you're located, they may decide to come out again because they just surveyed you and it's going to be another three years and that's a long time to wait.

(Debbie Berringer): Okay.

Sandra Bastinelli: So it's - just make sure you let both the NSC and the - update your application and just call your accrediting organization's customer service line.

(Debbie Berringer): Okay. All right. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question comes from (Dennis Gray). Your line is open.

Sandra Bastinelli: Hi, (Dennis)?

(Dennis Gray): Yes. I had a question on this. I heard a rumor there might be a more lax application for someone filling strips and that's (unintelligible) diabetic strips. And also (unintelligible) participating pharmacy - that's a pharmacy

that (expects) a (unintelligible) and a non participating pharmacy is one that who does not (expect) a (unintelligible), is that correct?

Sandra Bastinelli: You know, I am not the expert there on non participating - and it sounds like we have some people on the phone that are more than, but I don't know if that is true. If you can give me that on email, I'll be happy to clarify. And certainly (some) of you have had questions about participating and non participating. I will get something out on the listserv so everyone has the knowledge of that. I'd be happy to do that.

But if you don't mind, sir, just send me an email at Sandra....

(Dennis Gray): But the more laxed application for (unintelligible)...

Sandra Bastinelli: Regarding the more laxed application, I have no idea where that's coming from. The only thing I can think of is certainly your survey based on the complexity of your supplies will take longer. The least complicated of supplies, if you're only offering supply, it's going to be very short.

So (unintelligible) - well you may consider it the survey laxed but it's a lot shorter, you know, it just depends on your complexity, but has nothing to do with that you're just offering diabetic supplies because we've had major, you know, a couple of years ago a recall was used on the glucose monitors.

So, no, they look at every supply as being very important but the surveyor just has less to do, less to look at.

(Dennis Gray): And did I hear you correctly, you've already signed up 25,000 pharmacies?

Sandra Bastinelli: Yes, yes, locations.

(Dennis Gray): That's 25,000 accredited pharmacies \$4000 a pharmacy, that's \$100 million - that's a lot of money, isn't it?

Sandra Bastinelli: To whom? Oh it's not - it doesn't go to CMS, sir.

(Dennis Gray): Oh, okay.

Sandra Bastinelli: No, no. Let me explain for everyone on the phone (unintelligible)...

(Dennis Gray): (Unintelligible) bureaucratic (unintelligible) dollars, right?

Sandra Bastinelli: No, no. It has nothing to do with CMS. Thank you for asking that question. I would be happy to answer that. Our accrediting organizations charged for their services, much like any other organization would. We at CMS are not contracted. We do not spend any money from our Congressional budget or otherwise to - that we get paid from either the supplier or the accrediting organization.

The money changes hands from the accrediting organization and the supplier. So the money that you are adding up in your head actually doesn't even add because that represents probably eight of the ten accrediting organizations that accredited those chains.

So they - not one organization got that money. And it is a costly program certainly with the survey activities, the staff that are highly qualified to provide that service and also the travel cost. Someone has to pay for those travel costs. But we at CMS do not receive any of that money, no.

(Dennis Gray): I really didn't imply that. I just thought that was a lot of money especially if you only have 25,000 pharmacies signed up at this time. How many pharmacies total do you anticipate on enrolling in this program?

Sandra Bastinelli: That I do not know, sir.

(Dennis Gray): Okay. How many pharmacies are out there in the United States?

Sandra Bastinelli: I don't have the statistics in hand because they do - the pharmacies do come in as different - they come in as part of a department store, part of a grocery store. We have 54,000 supplier locations and we have some that are department or grocery stores as well. But the bulk are 54,000 pharmacy locations.

(Dennis Gray): So you've got \$220 million every three years then, right.

Sandra Bastinelli: Sir, I'm not sure what the money, I don't know. I don't know what that has - I just don't - I'm sorry, I'm missing your point and I apologize for being dense.

(Dennis Gray): I think everybody else is getting it though. Okay. Thank you.

Sandra Bastinelli: Oh, that's good.

Natalie Highsmith: Next question, please.

Operator: The next question comes from (Don Thomas). Your line is open.

(Don Thomas): Yes, (Don Thomas), (Saint Mary)'s, West Virginia. Do you have to be accredited to bill the Advantage Plans, the Part B Advantage Plans?

Sandra Bastinelli: No, this does not - thank you for the question. This is a fee for service accreditation rule and it is not under the Medicare Advantage part of the regulation.

(Don Thomas): Very good. Thank you.

Sandra Bastinelli: You're welcome.

Operator: And at this time we have no further questions.

Natalie Highsmith: Okay. Perfect timing because it is 3:30 here on the East coast. I'll turn it over to Sandra for any closing remarks.

Sandra Bastinelli: Thank you Natalie. Thank you so very much for everyone that has called in and has asked questions. And hopefully we were somewhat helpful. For those of you who we were not able to answer your questions, please forward those emails.

And my next step I did promise that I would give you an email about non assigning and assignment of benefits and I'll be happy to do so by way of the listserv. Okay and good luck with all of your efforts. And for any of the pharmacists that have further questions that I can answer here in CMS that is within my authority to answer, I will be happy to do so.

And again, thanks so much for all of your time. Bye now.

Natalie Highsmith: (Alesia) can you tell us how many people joined us on the phone line?

Operator: Yes, ma'am, we have 340 participants.

Natalie Highsmith: Three forty, wonderful. Thank you everyone.

Operator: This concludes today's conference call. You may now disconnect.

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